PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PRON-034 PCT	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IL04/01115	International filing date *(day/month/year)* 09 December 2004 (09.12.2004)	Priority date *(day/month/year)* 09 December 2003 (09.12.2003)
International Patent Classification (IPC) or national classification and IPC IPC: A61K 38/00(2006.01),35/12(2006.01),39/00(2006.01);C12N 5/02(2006.01) USPC: 424/185.1;514/2;435/325		
Applicant YEDA RESEARCH AND DEVELOPMENT CO. LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☒ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 March 2006 (30.03.2006)	01 September 2006 (01.09.2006)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Kimberly A. Ballard J. Roberts for Telephone No. 571-272-0500

Form PCT/IPEA/409 (cover sheet)(April 2005)

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Box No. I Basis of the report

1. With regard to the language, this report is based on:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4(a))

☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☐ the international application as originally filed/furnished

☒ the description:
pages 1-46 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☒ the claims:
pages NONE as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 47-53 received by this Authority on 30 March 2006 (30.03.2006)
pages* NONE received by this Authority on _____

☒ the drawings:
pages 1-24 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____
☐ the claims, Nos _____
☐ the drawings, sheets/figs _____
☐ the sequence listing (*specify*): _____
☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 6-13,33-40 and 48-55

because:

☐ the said international application, or the said claim Nos. ____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 6-13,33-40 and 48-55 are so unclear that no meaningful opinion could be formed *(specify)*:

The claims are improper multiple dependent claims under PCT Rule 6.4(a) or are dependent from improper multiple dependent claims.

☐ the claims, or said claims Nos. ____ are so inadequately supported by the description that no meaningful opinion could be formed *(specify)*:

☐ no international search report has been established for said claims Nos. ____

☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.

☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 32, 45	YES
	Claims 1-5, 14-31, 41-44, 46-47, 56-58	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-5, 14-32, 41-47 and 56-58	NO
Industrial Applicability (IA)	Claims 1-5, 14-32, 41-47, 56-58	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)
Please See Continuation Sheet

Form PCT/IPEA/409 (Box No. V) (April 2005)

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 41-47 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims 41-47 are indefinite for the following reason(s): The claims are considered "use" claims and are indefinite as to whether they are method or product claims. For purposes of the IPER, the claims have been interpreted as product claims.

Form PCT/IPEA/409 (Box No. VIII) (April 2005)

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

V. 2. Citations and Explanations:
Claims 1-5, 14-32, 41-47, and 56-58 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 32 and 45 meet the criteria set out in PCT Article 33(2), because the prior art does not teach or fairly suggest the claimed invention therein.

Claims 1-4, 14-16, 18-28, 30, 41-43, 46, 47, and 56-58 lack novelty under PCT Article 33(2) as being anticipated by Schwartz (2001). Schwartz teaches vaccination with Copolymer 1 (Cop-1) as a candidate for effective therapy of numerous neurodegenerative diseases (p. 624). Copolymer-1 (Cop-1) is a synthetic amino-acid copolymer composed of four amino acids (L-alanine, L-lysine, L-glutamic acid, and L-tyrosine) in a defined molar ratio (see Sela (2000), p. 66). There is no specific sequence or length requirement for Cop-1, therefore Cop-1-related peptides and polypeptides would be encompassed by Copolymer-1 itself. Neurodegenerative disease falls under the definition of psychiatric diseases, disorders and conditions (as defined on p. 5-6 of the instant disclosure), and a vaccination using Cop-1 would be encompassed by the pharmaceutical composition, vaccine, use of these agents and method of treatment.

Claims 14-30, 41-43, 46, 47, and 56-58 lack novelty under PCT Article 33(2) as being anticipated by Kipnis et al. (2000). Kipnis et al. teach vaccination with Copolymer 1 (Cop-1) and an adjuvant to rats. Kipnis also teaches the activation of T cells with Cop-1 and the administration of these activated T cells to a rat (p. 7447). These teachings would therefore anticipate the pharmaceutical composition of claims 14-25 and 41, the vaccine claims 26-30, 42-43 and 46-47, and the articles of manufacture of claims 56-58.

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Supplemental Box

Claims 1-4, 14-16, 18-28, 30, 41-43, 46, 47, and 56-58 lack novelty under PCT Article 33(2) as being anticipated by Kipnis and Schwartz (2002). Kipnis and Schwartz teach the use of glatiramer acetate (Cop-1) as a therapeutic vaccine for the treatment of neurodegenerative disorders (see p. 320, 2nd column). Copolymer-1 (Cop-1) is a synthetic amino-acid copolymer composed of four amino acids (L-alanine, L-lysine, L-glutamic acid, and L-tyrosine) in a defined molar ratio (see p. 320, 1st column, and Sela (2000), p. 66). There is no specific sequence or length requirement for Cop-1, therefore Cop-1-related peptides and polypeptides would be encompassed by Copolymer-1 itself. Neurodegenerative disease falls under the definition of psychiatric diseases, disorders and conditions (as defined on p. 5-6 of the instant disclosure) and would therefore be anticipated by Kipnis and Schwartz, as would the broader claims directed to vaccines, pharmaceutical compositions, articles of manufacture, and use of these agents recited in the other claims.

Claims 1-5, 14-31, 41-44, 46, 47 and 56-58 lack novelty under PCT Article 33(2) as being anticipated by US Patent Application 2002/0037848 (No. 09/765,301) by Eisenbach-Schwartz et al. (published March 28, 2002). US Patent Application 09/765,301 teaches the use of Copolymer-1 (Cop-1), Cop 1-related peptides or polypeptides, as well as T-cells activated by Cop 1 or Cop 1-related peptides or polypeptides in neurodegenerative diseases such as Alzheimer's disease, Parkinson's disease, vitamin deficiency, prion diseases such as Creutzfeldt-Jakob disease and others (see p. 7 [0069], p. 10 [0097], and p. 11 [0103]). The '301 application further teaches the use of vaccines comprising Cop-1 with and without adjuvants (p. 10-11 [0101]), and pharmaceutical compositions comprising Cop-1 or related peptides and polypeptides (p. 11 [0104-0107]).

Claims 32 and 45 lack an inventive step under PCT Article 33(3) as being obvious over US Patent Application 2002/0037848 (No. 09/765,301, Eisenbach-Schwartz et al., published March 28, 2002) in view of Ulmer et al. (1999). The claims are drawn to a vaccine for immunization of an individual suffering from a psychiatric disorder, disease or condition comprising an active agent selected from Cop-1, and Cop-1 peptides or polypeptides, wherein said vaccine comprises the active agent emulsified in an adjuvant suitable for human clinical use, wherein the adjuvant is selected from aluminum hydroxide, aluminum hydroxide gel, and aluminum hydroxyphosphate.

US Patent Application '301 teaches use a vaccination comprising Cop-1 with an adjuvant for the treatment of neurodegenerative diseases (see p. 11, paragraph 0101). However, the '301 application does not specifically teach the use of the aluminum-based adjuvants with Cop-1 for a vaccine.

Ulmer et al. teach the use of aluminum adjuvants, including aluminum hydroxide and aluminum hydroxyphosphate (p. 19) in the production of DNA vaccines. Ulmer et al. report that the aluminum salt adjuvants, which are currently licensed for human use (p. 19), strongly enhanced the immune responses induced by DNA vaccines administered to mice (p. 27). Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to arrive at the claimed invention by combining the methods of using a Cop-1 vaccine as taught by US Patent Application '301 with the methods of increasing the potency of the vaccine using specific aluminum adjuvants as taught by Ulmer et al. to produce a vaccine comprising Cop-1 and an potent adjuvant suitable for human use.

With regard to applicant amendments/remarks filed 30 March 2006, claims 32 and 45 are now indicated as meeting the criteria set out in PCT Article 33(2). Applicant's arguments for each reference will be addressed in turn.

NOVELTY

SCHWARTZ (2001) With regard to claims 1-4, Applicant argues that Schwartz's disclosure of treatment of neurodegenerative diseases does not anticipate psychiatric disorders because neurodegenerative diseases would not be encompassed by psychiatric disorders. However, claims 1-4 are broadly drawn to a method of treating "a psychiatric disorder, disease or condition" and the instant specification notes at p. 5-6 that such a disorders include "memory loss associated with Alzheimer's type dementia" and other neurodegenerative diseases and disorders. Thus, treatment of neurodegenerative disease as taught by Schwartz would still anticipate the claimed treatment method, as the patient populations would be the same. Additionally, the intended use for the products - i.e., pharmaceutical compositions, vaccines and articles of manufacture (claims 14-16, 18-28, 30, 41-43, 46, 47, and 56-58) - does not distinguish the products themselves from those taught in the prior art, because a product and all of its properties are inseparable. Accordingly, the products are anticipated by Schwartz (2001).

KIPNIS et al. (2000) Applicant argues that Kipnis et al. (2000) do not mention psychiatric disorders in the article and thus would not anticipate the present pharmaceutical claims 14-25 and 41, the vaccine claims 26-30, 42-43, and 46-47, and the articles of manufacture claims 56-58. However, it is noted that the intended use for these claimed products does not distinguish the products themselves from those taught in the prior art, because a product and all of its properties are inseparable. Accordingly, the products are anticipated by Kipnis et al. (2000).

KIPNIS & SCHWARTZ (2002) Applicant argues that Kipnis & Schwartz (2002) describe the use of Cpo-1 in the treatment of multiple sclerosis and do not mention psychiatric disorders, and therefore do not anticipate the instant claims. However, claims 1-4

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are broadly drawn to a method of treating "a psychiatric disorder, disease or condition" and the instant specification notes at p. 5-6 that such a disorders include "memory loss associated with Alzheimer's type dementia" and other neurodegenerative diseases and disorders. Thus, treatment of neurodegenerative disease as taught by Kipnis & Schwartz would still anticipate the claimed treatment method, as the patient populations would be the same. Additionally, the intended use for the products - i.e., pharmaceutical compositions, vaccines and articles of manufacture (claims 14-16, 18-28, 30, 41-43, 46, 47, and 56-58) - does not distinguish the products themselves from those taught in the prior art, because a product and all of its properties are inseparable. Accordingly, the products are anticipated by Kipnis & Schwartz (2002).

US 2002/0037848 (US Patent Application No. 09/765,301) Applicant argues that the disclosure of treatment of neurodegenerative disease would not anticipate the instantly claimed method of treating psychiatric disorders. For the reasons addressed above in Schwartz (2001) and Kipnis & Schwartz (2002), the prior art still anticipates present claims 1-5, 14-31, 41-44, 46, 47 and 56-58.

FEINSTEIN (2000) Applicant's arguments regarding the teachings of Feinstein and application to the present invention are persuasive. The anticipation of the present claims by Feinstein under PCT Article 33(2) is withdrawn.

INVENTIVE STEP

US 2002/0037848 (US Patent Application No. 09/765,301) in view of ROTHERMUNDT et al. (2001) and TEITELBAUM et al. (1997) The negative statement regarding previous claims 7, 14, 24 and 35 for lack of inventive step is rendered moot in view of Applicant's amendments to the present claims.

US 2002/0037848 (US Patent Application No. 09/765,301) in view of ULMER et al. (1999) The lack of inventive step regarding the combination of these references was not addressed by Applicant.

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CLAIMS:

1. A method for treatment of a psychiatric disorder, disease or condition, which comprises administering to an individual in need of such a treatment an effective amount of an agent selected from the group consisting of (i) Copolymer 1, (ii) a Copolymer 1-related peptide, (iii) a Copolymer 1-related polypeptide, and (iv) T cells activated with (i), (ii) or (iii).

2. A method according to claim 1 wherein said individual is immunized with a therapeutically effective amount of an agent selected from the group consisting of Copolymer 1, a Copolymer 1-related peptide, and a Copolymer 1-related polypeptide.

3. The method according to claim 1 or 2 wherein said agent is Copolymer 1.

4. The method according to claim 1 or 2 wherein said agent is a Copolymer 1-related peptide or a Copolymer 1-related polypeptide.

5. The method according to claim 1 wherein said agent is T cells which have been activated by Copolymer 1.

6. A method according to any of claims 1 to 5 wherein said psychiatric disorder, disease or condition is selected from the group consisting of: (i) anxiety disorders; (ii) mood disorders; (iii) schizophrenia and related disorders; (iv) drug use and dependence; and (v) memory loss disorders.

7. A method according to claim 6 wherein said anxiety disorders include phobic disorders, obsessive-compulsive disorder, stress, post-traumatic stress disorder (PTSD), acute stress disorder and generalized anxiety disorder.

8. A method according to claim 7 wherein said anxiety disorder is post-traumatic stress disorder (PTSD) and said agent is Copolymer 1.

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Amended

9. A method according to claim 6 wherein said mood disorders include depression, dysthymic disorder, bipolar disorders and cyclothymic disorder.

10. A method according to claim 6 wherein said psychiatric disorder, disease or condition is schizophrenia and said agent is Copolymer 1.

11. A method according to claim 6 wherein said schizophrenia related disorders include brief psychotic disorder, schizophreniform disorder, schizoaffective disorder and delusional disorder.

12. A method according to claim 6 wherein said drug use and dependence include alcoholism, cocaine dependence, amphetamine dependence, hallucinogen dependence, and phencyclidine use.

13. A method according to claim 6 wherein said memory loss disorder is cognitive impairment.

14. A pharmaceutical composition for treatment of a psychiatric disorder, disease or condition comprising a pharmaceutically acceptable carrier and an active agent selected from the group consisting of (i) Copolymer 1, (ii) a Copolymer 1-related peptide, (iii) a Copolymer 1-related polypeptide, and (iv) T cells activated with (i), (ii) or (iii).

15. A pharmaceutical composition according to claim 14, wherein said active agent is Copolymer 1.

16. A pharmaceutical composition according to claim 14, wherein said agent is a Copolymer 1-related peptide or a Copolymer 1-related polypeptide.

17. A pharmaceutical composition according to claim 14, wherein said agent is T cells which have been activated by Copolymer 1.

18. A pharmaceutical composition according to any one of claims 14 to 17 wherein said psychiatric disorder, disease or condition is selected from the group

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consisting of: (i) anxiety disorders; (ii) mood disorders; (iii) schizophrenia and related disorders; (iv) drug use and dependence; and (v) memory loss disorders.

19. A pharmaceutical composition according to claim 18 wherein said anxiety disorders include phobic disorders, obsessive-compulsive disorder, stress, post-traumatic stress disorder (PTSD), acute stress disorder and generalized anxiety disorder.

20. A pharmaceutical composition according to claim 19 wherein said anxiety disorder is post-traumatic stress disorder (PTSD) and said agent is Copolymer 1.

21. A pharmaceutical composition according to claim 18 wherein said mood disorders include depression, dysthymic disorder, bipolar disorders and cyclothymic disorder.

22. A pharmaceutical composition according to claim 18 wherein said psychiatric disorder, disease or condition is schizophrenia and said agent is Copolymer 1.

23. A pharmaceutical composition according to claim 18 wherein said schizophrenia related disorders include brief psychotic disorder, schizophreniform disorder, schizoaffective disorder and delusional disorder.

24. A pharmaceutical composition according to claim 23 wherein said drug use and dependence include alcoholism, cocaine dependence, amphetamine dependence, hallucinogen dependence, and phencyclidine use.

25. A pharmaceutical composition according to claim 18 wherein said memory loss disorder is cognitive impairment.

26. A vaccine for immunization of an individual suffering from a psychiatric disorder, disease or condition comprising an active agent selected from the group consisting of Copolymer 1, a Copolymer 1-related peptide, and a Copolymer 1-related polypeptide.

27. A vaccine according to claim 26 wherein said active agent is Copolymer 1.

28. The vaccine according to claim 26 wherein said agent is a Copolymer 1-related peptide or a Copolymer 1-related polypeptide.

29. A vaccine according to claim 14, wherein said agent is 'I' cells which have been activated by Copolymer 1.

30. A vaccine according to any one of claims 26 to 29 wherein said vaccine comprises the active agent without an adjuvant.

31. A vaccine according to any one of claims 26 to 29 wherein said vaccine comprises the active agent emulsified in an adjuvant suitable for human clinical use.

32. A vaccine according to claim 31 wherein said adjuvant is selected from the group consisting of aluminum hydroxide, aluminum hydroxide gel, and aluminum hydroxyphosphate.

33. A vaccine according to any one of claims 26 to 32 for immunization wherein said psychiatric disorder, disease or condition is selected from the group consisting of: (i) anxiety disorders; (ii) mood disorders; (iii) schizophrenia and related disorders; (iv) drug use and dependence; and (v) memory loss disorders.

34. A vaccine according to claim 33 wherein said anxiety disorders include phobic disorders, obsessive-compulsive disorder, stress, post-traumatic stress disorder (PTSD), acute stress disorder and generalized anxiety disorder.

35. A vaccine according to claim 34 wherein said anxiety disorder is post-traumatic stress disorder (PTSD) and said agent is Copolymer 1.

36. A vaccine according to claim 33 wherein said mood disorders include depression, dysthymic disorder, bipolar disorders and cyclothymic disorder.

37. A vaccine according to claim 33 wherein said psychiatric disorder, disease or condition is schizophrenia and said agent is Copolymer 1.

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Amended

38. A vaccine according to claim 33 wherein said schizophrenia related disorders include brief psychotic disorder, schizophreniform disorder, schizoaffective disorder and delusional disorder.

39. A vaccine according to claim 33 wherein said drug use and dependence include alcoholism, cocaine dependence, amphetamine dependence, hallucinogen dependence, and phencyclidine use.

40. A vaccine according to claim 33 wherein said memory loss disorder is cognitive impairment.

41. Use of an agent selected from the group consisting of (i) Copolymer 1, (ii) a Copolymer 1-related peptide, (iii) a Copolymer 1-related polypeptide, and (iv) T cells activated with (i), (ii) or (iii), for the preparation of a pharmaceutical composition for treatment of a psychiatric disorder, disease or condition.

42. Use of an agent selected from the group consisting of Copolymer 1, a Copolymer 1-related peptide, and a Copolymer 1-related polypeptide, for the preparation of a vaccine for immunization of an individual suffering from a psychiatric disorder, disease or condition.

43. Use according to claim 42 wherein said vaccine comprises the active agent without an adjuvant.

44. Use according to claim 42 wherein said vaccine comprises the active agent emulsified in an adjuvant suitable for human clinical use.

45. Use according to claim 44, wherein said adjuvant is selected from the group consisting of aluminum hydroxide, aluminum hydroxide gel, and aluminum hydroxyphosphate.

46. Use according to any one of claims 42 to 45 wherein said active agent is Copolymer 1.

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47. Use according to any one of claims 42 to 45 wherein said active agent is a Copolymer 1-related peptide or a Copolymer 1-related polypeptide.

48. Use according to according to any one of claims 41 to 47 wherein said psychiatric disorder, disease or condition is selected from the group consisting of: (i) anxiety disorders; (ii) mood disorders; (iii) schizophrenia and related disorders; (iv) drug use and dependence; and (v) memory loss disorders.

49. Use according to claim 48 wherein said anxiety disorders include phobic disorders, obsessive-compulsive disorder, stress, post-traumatic stress disorder (PTSD), acute stress disorder and generalized anxiety disorder.

50. Use according to claim 49 wherein said anxiety disorder is post-traumatic stress disorder (PTSD) and said agent is Copolymer 1.

51. Use according to claim 48 wherein said mood disorders include depression, dysthymic disorder, bipolar disorders and cyclothymic disorder.

52. Use according to claim 48 wherein said psychiatric disorder, disease or condition is schizophrenia and said agent is Copolymer 1.

53. Use according to claim 48 wherein said schizophrenia related disorders include brief psychotic disorder, schizophreniform disorder, schizoaffective disorder and delusional disorder.

54. Use according to claim 48 wherein said drug use and dependence include alcoholism, cocaine dependence, amphetamine dependence, hallucinogen dependence, and phencyclidine use.

55. Use according to claim 48 wherein said memory loss disorder is cognitive impairment.

56. An article of manufacture comprising packaging material and a pharmaceutical composition contained within the packaging material, said

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pharmaceutical composition comprising an agent selected from the group consisting of Copolymer 1, a Copolymer 1-related peptide, and a Copolymer 1-related polypeptide; and said packaging material includes a label that indicates that said agent is therapeutically effective for treating a psychiatric disorder.

57. An article of manufacture comprising packaging material and a pharmaceutical composition contained within the packaging material, said pharmaceutical composition comprising Copolymer 1; and said packaging material includes a label that indicates that Copolymer 1 is therapeutically effective for treating a psychiatric disorder.

58. The article of manufacture of claim 56 or 57 wherein said psychiatric disorder is selected from: (i) anxiety disorders; (ii) mood disorders; (iii) schizophrenia and related disorders; (iv) drug use and dependence; and (v) memory loss disorders.

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